This is an official

MS Health Alert Network (HAN) Alert

MESSAGE ID: MSHAN-20210815-00529-ALT (Health Alert)

RECIPIENTS: All Physicians, Hospitals, ERs, ICPs, NPs, and

Healthcare Providers - Statewide

Sunday, August 15, 2021

SUBJECT: Mississippi Statewide Standing Order for REGEN-COV

Monoclonal Antibodies Effective August 16, 2021

Administration of REGEN-COV Monoclonal Antibodies for COVID-19

Purpose:

To reduce morbidity and mortality from SARS-CoV-2, the virus that causes COVID-19, by treating all persons who meet the treatment criteria established by the U.S. Food and Drug Administration (FDA) outlined in the Emergency Use Authorization (EUA) for the REGEN-COV monoclonal antibody product.

Policy:

Under these standing orders, eligible healthcare providers are authorized to administer REGEN-COV to adults and adolescents 12 years of age and older weighing at least 40 kg with positive results of direct SARS-CoV-2 testing within 10 days of symptom onset who meet any of the criteria below.

- i. Older age (for example, age \geq 65 years of age)
- ii. Obesity or being overweight (for example, BMI >25 kg/m², or if age 12-17, have BMI ≥85th percentile for their age and gender)
- iii. Pregnancy
- iv. Chronic kidney disease
- v. Diabetes
- vi. Immunosuppressive disease or immunosuppressive treatment
- vii. Cardiovascular disease (including congenital heart disease) or hypertension
- viii. Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- ix. Sickle cell disease
- x. Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- xi. Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))
- xii. Other medical conditions or factors (such as race and ethnicity) that may place individuals at an increased risk for progression to more severe disease. Authorization of REGEN-COV under the current EUA is not limited to the medical conditions or factors listed above.



Monoclonal antibodies are <u>not authorized</u> for use in patients:

- i. Who are hospitalized due to COVID-19, OR
- ii. Who require oxygen therapy due to COVID-19, OR
- iii. Who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.

The guidance in the EUA for the monoclonal antibodies can change frequently. Please refer to the reference below for the latest guidance.

Regeneron Pharmaceuticals: <u>treatment-covid19-eua-fact-sheet-for-hcp.pdf</u> (<u>regeneron.com</u>)

Order to dispense:

The healthcare provider is authorized to dispense the below formulations of monoclonal antibodies:

REGEN-COV (casirivimab and imdevimab)

- Formulations
 - O Single product vials: Casirivimab 120 mg/mL - 5mL total (from 2.5 or 11.1 mL vials) for 600 mg casirivimab Imdevimab 120 mg/mL - 5mL total (from 2.5 or 11.1 mL vials) for 600 mg imdevimab
 - Co-formulated vials:
 Casirivimab and imdevimab 60 mg/mL 10mL total for 600 mg casirivimab and imdevimab

The patient must be provided a copy of the Patient Fact Sheet:

- English: treatment-covid19-eua-fact-sheet-for-patient.pdf (regeneron.com)
- Spanish: treatment-covid19-eua-fact-sheet-patient-spanish.pdf (regeneron.com)

Preparation:

INTRAVENOUS INFUSION

Size of Prefilled 0.9% Sodium Chloride Infusion Bag	Preparing 600 mg of Casirivimab and 600 mg of Imdevimab Using Co- Formulated Vial	Preparing 600 mg of Casirivimab and 600 mg of Imdevimab Using Individual Vials
50 mL 100 mL	Add 10 mL of co-formulated casirivimab and imdevimab (1 vial) into a prefilled 0.9% sodium chloride infusion bag and administer as instructed	Add: • 5 mL of casirivmab (may use 2 vials of 2.5 mL OR 5 mL from 1 vial of 11.1 mL)
150 mL		• 5 mL of imdevimab (may use 2 vials of 2.5 mL OR 5 mL from 1 vial of 11.1 mL)



250 mL	Inject into prefilled 0.9% sodium
	chloride infusion bag and
	administer as instructed below

SUBCUTANEOUS INJECTION

Prepare 600 mg of Casirivimab and 600 mg of Imdevimab	Preparation of 4 syringes
Using Co-Formulated Vial	Withdraw 2.5 mL solution per syringe into FOUR separate syringes
Using Individual Vials	Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes

Administration:

INTRAVENOUS INFUSION

- For the administration of 600 mg of casirivimab and 600 mg of imdevimab, gather the recommended materials for infusion:
- Polyvinyl chloride (PVC), polyethylene (PE)-lined PVC, or polyurethane (PU) infusion set, inline or add-on 0.2-micron polyethersulfone (PES) filter
- Attach the infusion set to the intravenous bag
- Prime the infusion set
- Administer the entire infusion solution in the bag via pump or gravity through an intravenous line containing a sterile, in-line or add-on 0.2-micron polyethersulfone (PES) filter at the specified rate below

Size of Prefilled 0.9% Sodium Chloride Infusion Bag Used	Maximum Infusion Rate	Minimum Infusion Time
50 mL	180 mL/hr	20 minutes
100 mL	310 mL/hr	21 minutes
150 mL	310 mL/hr	31 minutes
250 mL	310 mL/hr	50 minutes

- Due to potential overfill of prefilled saline bags, the entire infusion solution in the bag should be administered to avoid underdosage
- The prepared infusion solution should not be administered simultaneously with any other medication. The compatibility of casirivimab and imdevimab injection with intravenous solutions and medications other than 0.9% Sodium Chloride Injection is not known.
- After infusion is complete, flush the tubing with 0.9% Sodium Chloride Injection to ensure delivery of the required dose.



• Discard unused product.

SUBCUTANEOUS INJECTION

- For the administration of 600 mg of casirivimab and 600 mg of imdevimab, gather 4 syringes and prepare for subcutaneous injections.
- Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.
- When administering the subcutaneous injections, it is recommended that providers use different
 quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL
 subcutaneous injection of casirivimab and imdevimab. DO NOT inject into skin that is tender,
 damaged, bruised, or scarred.

Monitoring:

- Patients must be clinically monitored during administration of the medication AND observed for at least one-hour post-treatment to assess for potential adverse reactions.
- Proper treatments must be maintained on site for the management of rare anaphylactic reactions and the site must have the ability to activate EMS when needed.

Reporting and Recordkeeping:

- Healthcare providers must submit a report on all medication errors and ALL SERIOUS
 ADVERSE EVENTS potentially related to REGEN-COV. See EUA for instructions on reporting
 adverse events.
- A copy of the standing order signed by the Mississippi State Health Officer must be maintained on file and readily retrievable at each participating site.

Statement of Approval by the State Health Officer

The statewide standing order for monoclonal antibodies has been approved for use by authorized healthcare professionals from August 16, 2021 to October 1, 2021.

Thomas Dobbs, MD, MPH

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State Health Officer

Mississippi State Department of Health

August 15, 2021_____

Date



Alerting Message Specification Settings

Originating Agency: Mississippi State Department of Health Alerting Program: MS Health Alert Network (MS HAN)
Message Identifier: MSHAN-20210815-00529-ALT

Program (HAN) Type: Health Alert
Status (Type): Actual ()
Message Type: Alert

Reference: MSHAN-00529

Severity: Unknown

Acknowledgement: No

Sensitive: Not Sensitive
Message Expiration: Undetermined
Urgency: Undetermined
Delivery Time: 600 minutes

Definition of Alerting Vocabulary and Message Specification Settings

Originating Agency: A unique identifier for the agency originating the alert.

Alerting Program: The program sending the alert or engaging in alerts and

communications using PHIN Communication and Alerting (PCA)

as a vehicle for their delivery.

Message Identifier: A unique alert identifier that is generated upon alert activation

(MSHAN-yyymmdd-hhmm-TTT (ALT=Health Alert,

ADV=Health Advisory, UPD=Health Update,

MSG/INFO=Message/Info Service).

Program (HAN) Type: Categories of Health Alert Messages.

Health Alert: Conveys the highest level of importance; warrants immediate

action or attention.

Health Advisory: Provides important information for a specific incident or situation;

may not require immediate action.

Health Update: Provides updated information regarding an incident or situation;

unlikely to require immediate action.

Health Info Service: Provides Message / Notification of general public health

information; unlikely to require immediate action.

Status (Type):

Actual: Communication or alert refers to a live event Exercise: Designated recipients must respond to the

communication or alert

Test: Communication or alert is related to a technical,

system test and should be disregarded



Message Type:

Alert: Indicates an original Alert

Update: Indicates prior alert has been Updated and/or superseded

Cancel: Indicates prior alert has been cancelled Error: Indicates prior alert has been retracted

Reference: For a communication or alert with a Message Type of "Update" or "Cancel", this attribute contains the unique Message Identifier of the original communication or alert being updated or cancelled. "n/a" = Not Applicable.

Severity:

Extreme: Extraordinary threat to life or property
Severe: Significant threat to life or property
Moderate: Possible threat to life or property
Minor: Minimal threat to life or property
Unknown: Unknown threat to life or property

Acknowledgement: Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required (Yes or No).

Sensitive:

Sensitive: Indicates the alert contains sensitive content

Not Sensitive: Indicates non-sensitive content

Message Expiration: Undetermined.

Urgency: Undetermined. Responsive action should be taken immediately.

Delivery Time: Indicates the timeframe for delivery of the alert (15, 60, 1440,

4320 minutes (.25, 1, 24, 72 hours)).